BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**[EPA-HQ-OPP-2019-0274; FRL-8736-01-OCSPP]**

**Pesticide Experimental Use Permit; Receipt of Application; Comment Request**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** This notice announces EPA's receipt of an application 93167-EUP-2 from Oxitec, Ltd. requesting an amendment and extension to the experimental use permit (EUP) for the OX5034 *Aedes aegypti* mosquitoes expressing tetracycline Trans-Activator Variant (tTAV-OX5034) protein. The Agency has determined that the permit may be of regional and national significance. Therefore, because of the potential significance, EPA is seeking comments on this application.

**DATES:** Comments must be received on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2019-0274., by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

• *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets*.

**FOR FURTHER INFORMATION CONTACT:** Charles Smith, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *BPPDFRNotices@epa.gov*.

**SUPPLEMENTARY INFORMATION:**

## I. General Information

### *A. Does this Action Apply to Me?*

This action is directed to the public in general. Although this action may be of particular interest to those persons who conduct or sponsor research on pesticides, the Agency has not attempted to describe all the specific entities that may be affected by this action.

### *B. What Should I Consider as I Prepare My Comments for EPA?*

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments*. When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html*.

3. *Environmental justice*. EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticide(s) discussed in this document, compared to the general population.

**II. What Action is the Agency Taking?**

Under section 5 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. 136c, EPA can allow manufacturers to field test pesticides under development. Manufacturers are required to obtain an EUP before testing new pesticides or new uses of pesticides if they conduct experimental field tests on 10 acres or more of land or one acre or more of water.

Pursuant to 40 CFR 172.11(a), the Agency has determined that the following EUP amendment and extension application may be of regional and national significance, and therefore is seeking public comment on the EUP application:

*Submitter*: Oxitec, Ltd., (93167-EUP-2).

*Pesticide Chemical*: OX5034 *Aedes aegypti* mosquitoes expressing tetracycline Trans-Activator Variant (tTAV-OX5034) protein.

*Summary of Request*: Oxitec Ltd. is proposing to extend testing of OX5034 *Aedes aegypti* mosquitoes expressing tTAV-OX5034 protein for 2 years in the state of Florida up to 6,240 total acres at a maximum rate of 0.000082 g active ingredient (tTAV-

OX5034), equivalent to 20,000 male OX5034 mosquitoes, per acre, per week. Additionally, Oxitec Ltd is proposing to expand testing of OX5034 *Aedes aegypti* mosquitoes expressing tTAV-OX5034 protein in the state of California on up to 84,600 total acres at a maximum rate of 0.000123 g active ingredient (tTAV-OX5034), equivalent to 30,000 male OX5034 mosquitoes, per acre, per week. The proposed experiments are to evaluate the efficacy of OX5034 mosquitoes as a tool for suppression of wild *Aedes aegypti* mosquito populations. Female offspring of the OX5034 mosquitoes in the environment die before they mature into adults and therefore exposure to biting female mosquitoes is not anticipated.

EPA made its decision to grant the already issued Oxitec OX5034 Mosquito Experimental Use Permit in April 2020 after extensive evaluation of the best available science, and after seeking and addressing public input. EPA's risk assessment *https://www.regulations.gov/document/EPA-HQ-OPP-2019-0274-0359,* and response to comment document *https://www.regulations.gov/document/EPA-HQ-OPP-2019-0274-0354,* are publicly available and accessible through regulations.gov via these links. Common questions and answers regarding the already issued EUP can be found in the "The Experimental Use Permit for the Oxitec Genetically Engineered *Aedes aegypti* Mosquitoes" webinar available at *https://www.epa.gov/pesticides/biopesticides*.

Following the review of the application and any comments and data received in response to this solicitation, EPA will decide whether to issue or deny the EUP request, and if issued, the conditions under which it is to be conducted. Any issuance of an EUP will be announced in the *Federal Register*.

**Authority:** 7 U.S.C. 136 *et seq*.

Dated: August 25, 2021.

**Charles Smith,**

*Acting Director, Biopesticides and Pollution Prevention Division, Office of Pesticide*

*Programs.*

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